NOVEMBER 1996

COMPUTERWORLD HEALTHCARE JOURNAL

Living in the MATERIAL WORLD

PROVIDERS SEEK TO INTEGRATE SUPPLIES MANAGEMENT WITH CLINICAL, FINANCIAL SYSTEMS

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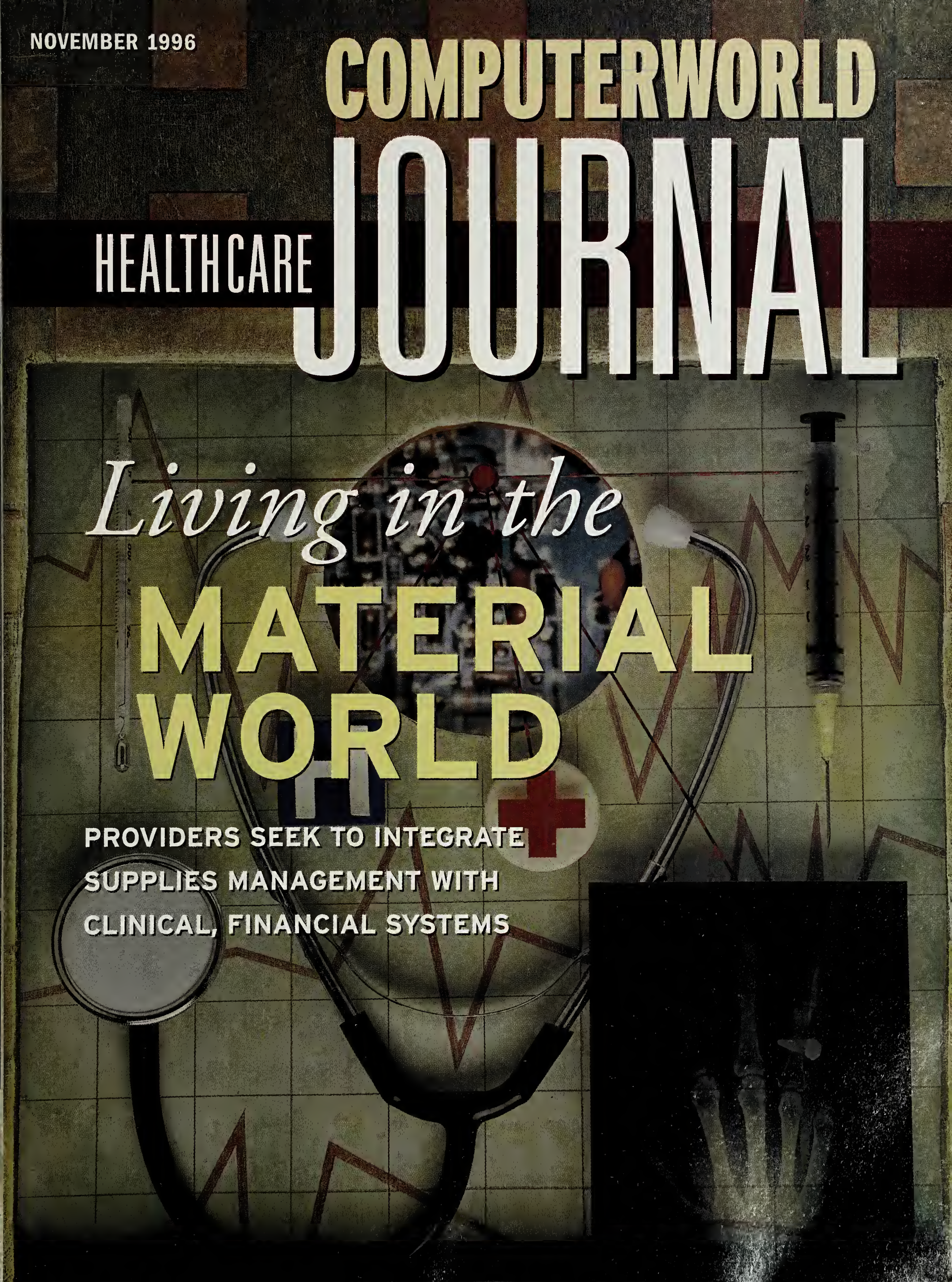
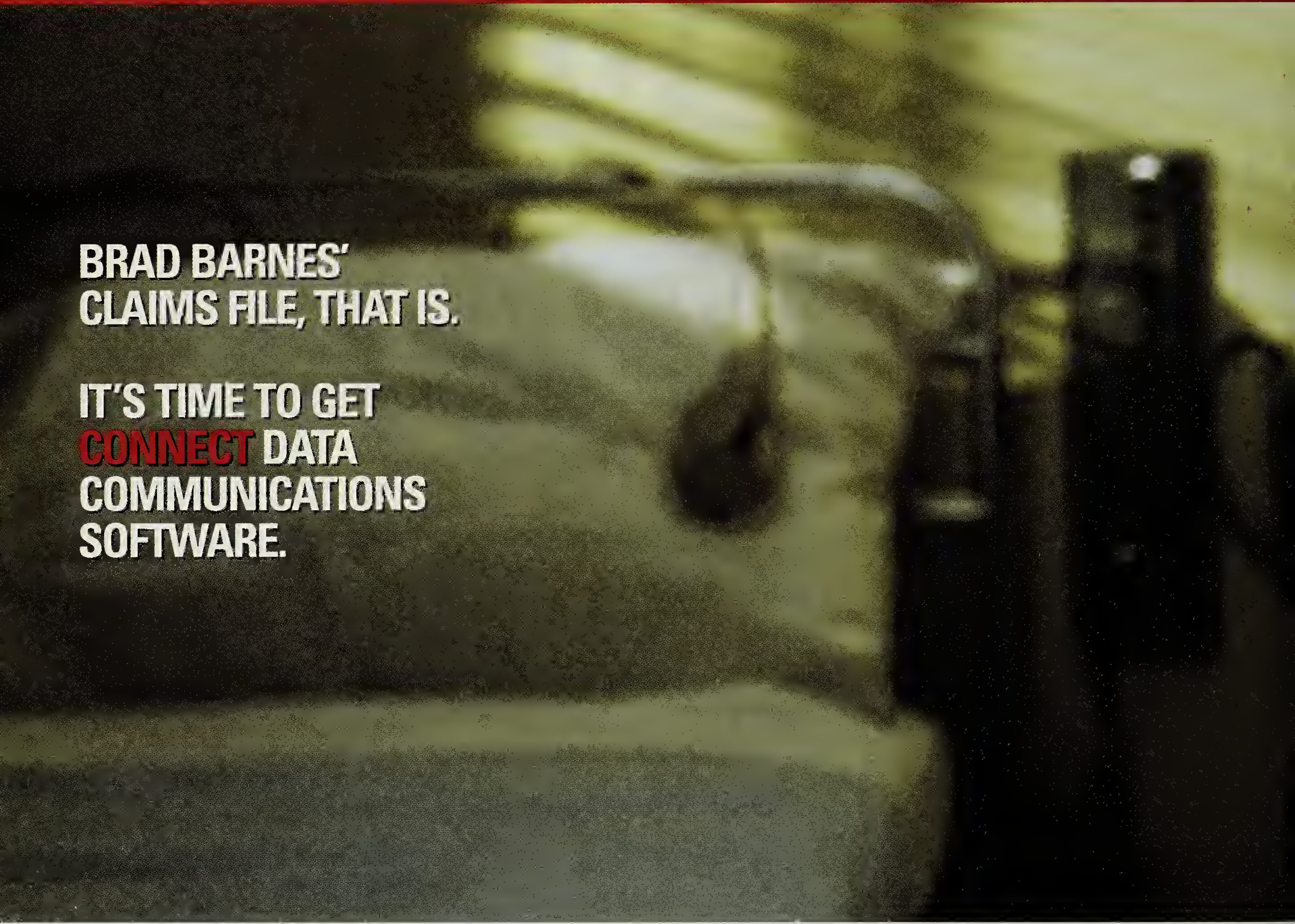


Living in the MATERIAL WORLD

PROVIDERS SEEK TO INTEGRATE SUPPLIES MANAGEMENT WITH CLINICAL, FINANCIAL SYSTEMS

BRAD BARNES NEVER MADE IT OUT OF THE HOSPITAL.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vitalsigns

A REVIEW OF HEALTHCARE TECHNOLOGY AND BUSINESS HAPPENINGS

Making Rural House Calls Over the Network

Houston hospital examines remote patients weekly via FDDI, T1 lines

BY WENDY MARX

The rural Rio Grande Valley area of Texas is rich in poverty and medical problems yet lacking in physicians with advanced training.

Consequently, the area has its share of medical horror stories, such as the one about the mother who quit her job to care for her severely brain-damaged little boy. Like most Rio Grande Valley residents, the mother couldn't afford to drive three hours to Corpus Christi, Texas, or seven hours to Houston to visit a specialist.

Today, the area still has its share of medical problems, but its 250,000 children are being served by world-class doctors from Texas Children's Hospital in Houston — the country's largest children's hospital, with 456 beds. It is also affiliated with Baylor College of Medicine. The Rio Grande Valley's good fortune is not a medical fairy tale but an example of how networking technology is revolutionizing healthcare, allowing "medical institutions to exchange clinical information and images across multiple providers and healthcare entities," said Cindy Patterson, a partner at Deloitte & Touche Consulting Group and head of its Northeast healthcare technology practice.

For Texas Children's Hospital, which has continued to improve on its circa 1991 high-speed network, networking is at the core of its business. Users are connected to 3Com Corp. FMS II hubs by shared 10M byte/sec. Ethernet connectors. Each hub has a dedicated 10M-byte line to a 3Com LANPlex 6000 switch. Services are connected to the LANPlex 6000 by a 100M byte/sec. Fiber Distributed Data Interface (FDDI) line.

Every Friday at the hospital's Houston facility, specialists remotely examine Rio Grande Valley children, listening to their hearts with a stethoscope, checking their vital signs and viewing their X rays. And because the system is interactive, the children and local primary care physicians can see and talk with the Houston doctors. The telehealth program uses dual television cameras and monitors that are linked by a 3Com NetBuilder Remote Access router to a hospital-based 3Com NetBuilder II, both of which are bridge routers with a modular design based on multiprocessor RISC architecture. Heartbeats are captured by a radio-controlled stethoscope with a microphone. The sound is multiplexed in with a video signal and sent over T1 lines.

Diagnostic images are digitized and compressed using Agfa-Gevaert Group software, which runs on Sun Microsystems, Inc. SPARCstation 10 workstations. The advantage to the hospital: less reliance on costly X-ray development and ready access by physicians to a patient's X rays.

MATT WAWIORKA

The hospital's geographically dispersed network is a far cry from a few years ago, when the information systems department at the hospital was "six people managing a Wang processor in a bank across from the hospital," said Jack Frost, the hospital's network manager. Because the departments weren't internetworked, patient information had to be entered into multiple systems.

Today, the 1,600-user network operates in a multivendor client/server environment that includes 1,200 Hewlett-Packard Co. 486-based PCs, 28 Novell, Inc. servers, nine Microsoft Corp. Windows NT servers and 12 Digital Equipment Corp. VAX superminicomputers. Since 1988, the hospital has spent in excess of $1.3 million in 3Com equipment. For the hospital, the expense has more than paid for itself.

"We could not possibly

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run our organization without information systems, and we couldn't possibly run those without the network," said Pat Perry, the hospital's vice president of information services. "People are able to access 30 different systems via PCs and the network" — everything from patient accounting and registration to an emergency room system.

The network is standardized on 3Com Transcend Networking, a scalable framework based on a broad range of networking solutions including FDDI, Asynchronous Transfer Mode and Ethernet and comprised of switches, hubs, routers, adapters and network management systems. Today, all of the hospital departments from billing and administration to pathology use the network, allowing all patient care areas to have access to patient records.

"We standardized on one vendor to stop the finger-pointing between multiple vendors," Frost explained. "Our network is providing direct patient care support. It has to be reliable."

> **HEARTBEATS** *are captured by a radio-controlled* **STETHOSCOPE** *with a* **MICROPHONE.**

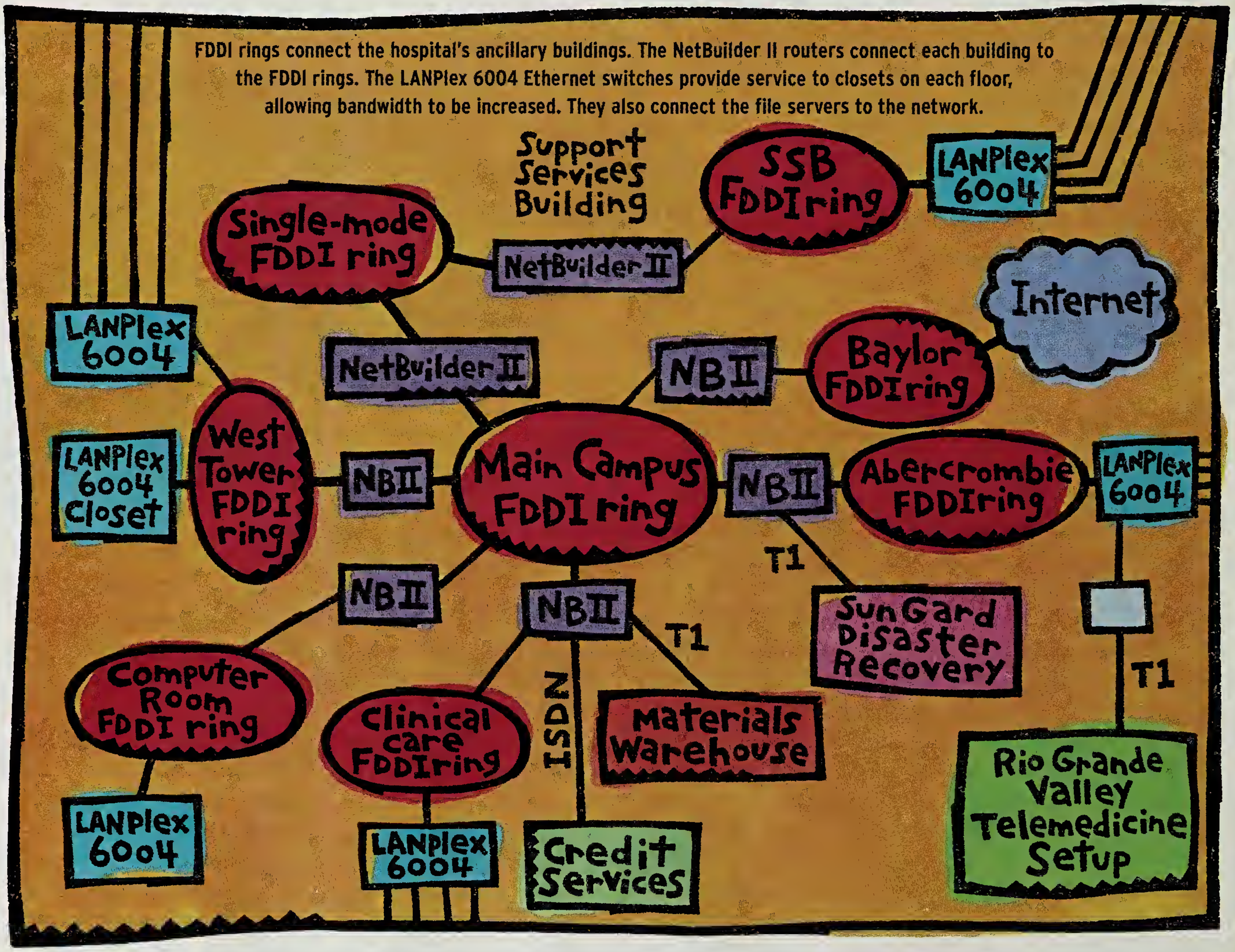
Future plans include centralizing all patient information so a clinician will be able to access one system for all patient data rather than going through multiple modules. The clinical records system will run on several Sun 6000 and 4000 computers.

"The goal of the network is to provide an infrastructure for us to access information just in time," said Greg Buffone, director of quality and outcomes management and a professor of pathology at Baylor.

His vision for the future? "That you as a physician, nurse or patient can access information whether you are at home or in an office site. The network provides the facility to get information." ■

MARX IS A FREELANCE WRITER IN STAMFORD, CONN.

NOTEWORTHY NET BENEFITS



FDDI rings connect the hospital's ancillary buildings. The NetBuilder II routers connect each building to the FDDI rings. The LANPlex 6004 Ethernet switches provide service to closets on each floor, allowing bandwidth to be increased. They also connect the file servers to the network.

MATT WAWIORKA

So Many Patients, So Little Time

Windows-based PatientEd software helps caregivers get more personal with patients

BY ROCHELLE GARNER

You're not alone if you don't think your doctor knows your name. Physicians treat too many patients. Patients see too many doctors for the same ailments. Individuals receive too little attention. In short, we live in an age of impersonal healthcare.

Now Medifor, Inc. in New Townsend, Wash., promises an easy antidote. Its prescription? PatientEd, new Windows-based software that lets primary-care physicians create personalized instructions, educational information and a medical history for each patient. The key, say physicians and nurses who are using the software, is that it takes only 60 to 90 seconds for physicians to input each patient's information.

"I had an older lady with Meniere's Disease [a problem with the inner ear] that caused her to get really dizzy," said Dr. Charles Zelnick, a family practice physician in Cedar Rapids, Iowa. "I found a template in PatientEd for Meniere's Disease, complete with a diagram to show her what part of her ear was infected, and knowing her medical history, I prescribed just the things I thought she should have."

The color handout he then printed contained both the patient's name and Dr. Zelnick's name and highlighted particular instructions that would be especially helpful. "She thought it was wonderful," he said.

Sounds great. However, users say, PatientEd also makes life easier for caregivers. Prescriptions, for example, can be checked off by box, then faxed to a pharmacist. What's more, those prescriptions remain in the patient's record for easier adjustment and updating when refilling. "I have one patient with 12 medications," Zelnick said. "I went right through the list — click, click, click — updated them just the way I wanted and printed out a whole page. It probably saved me a half hour in writing them, plus it's legible for the pharmacist."

PatientEd functions this way because it's built on Borland International, Inc.'s Paradox database for Windows. This database underpinning lets caregivers keep track of each patient encounter and choose from a variety of educational templates pertaining to the patient's specific disorder. This template can then be modified quickly by clicking on a list of medications, home care treatments and precautions. And since the information is updated by the caregiver at every patient encounter, the software can function as a minielectronic patient record.

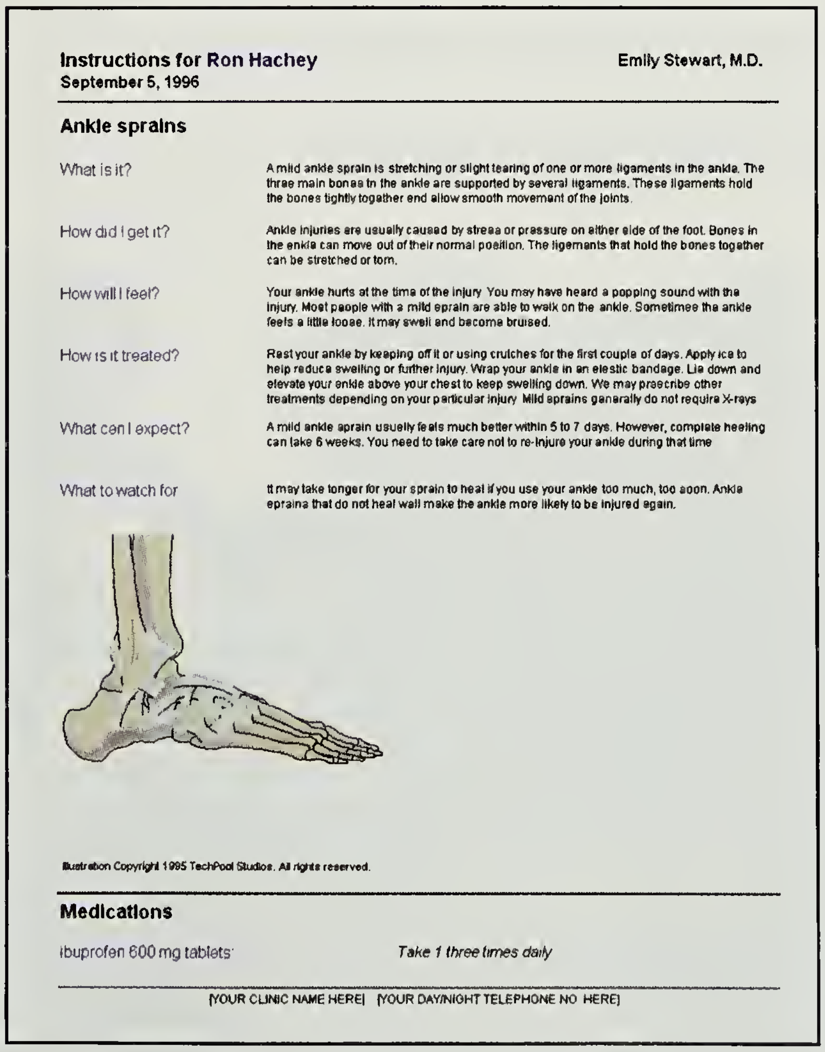
That's how Ken Brown, a registered nurse at Mats Mats Bay Healthcare Center in Port Ludlow, Wash., uses PatientEd. He provides follow-up reminders and keeps track of a patient's full encounter history. "The great thing is it takes only 90 seconds to point and click all of the instructions and to print them out," he explained.

The healthcare industry appears to like the sound of PatientEd, too. This past September, Physicians Insurance of Michigan began discounting malpractice insurance premiums by 2% for doctors who use the software. Medifor said it expects Physicians Insurance to soon offer similar discounts in five additional states.

PatientEd Version 1.0 runs on Microsoft Corp.'s Windows 3.1 and Windows 95 and supports both Windows NT and Novell, Inc. NetWare networks. Prices start at $795 for a stand-alone system and $295 for each additional concurrent user.

Version 1.5, due the beginning of next year, will include a drug interaction check and add formulary management, alerting physicians when a health plan pharmacy does not carry a particular medicine. ■

GARNER IS A FREELANCE WRITER IN SAN CARLOS, CALIF.



Instructions for Ron Hachey **Emily Stewart, M.D.**
September 5, 1996

Ankle sprains

What is it?	A mild ankle sprain is stretching or slight tearing of one or more ligaments in the ankle. The three main bones in the ankle are supported by several ligaments. These ligaments hold the bones tightly together and allow smooth movement of the joints.
How did I get it?	Ankle injuries are usually caused by stress or pressure on either side of the foot. Bones in the ankle can move out of their normal position. The ligaments that hold the bones together can be stretched or torn.
How will I feel?	Your ankle hurts at the time of the injury You may have heard a popping sound with the injury. Most people with a mild sprain are able to walk on the ankle. Sometimes the ankle feels a little loose. It may swell and become bruised.
How is it treated?	Rest your ankle by keeping off it or using crutches for the first couple of days. Apply ice to help reduce swelling or further injury. Wrap your ankle in an elastic bandage. Lie down and elevate your ankle above your chest to keep swelling down. We may prescribe other treatments depending on your particular injury Mild sprains generally do not require X-rays
What can I expect?	A mild ankle sprain usually feels much better within 5 to 7 days. However, complete healing can take 6 weeks. You need to take care not to re-injure your ankle during that time
What to watch for	It may take longer for your sprain to heal if you use your ankle too much, too soon. Ankle sprains that do not heal well make the ankle more likely to be injured again.

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Medications

Ibuprofen 600 mg tablets	*Take 1 three times daily*

[YOUR CLINIC NAME HERE] [YOUR DAY/NIGHT TELEPHONE NO HERE]

Based on Borland's Paradox, *PatientEd lets doctors customize instructions for their patients*

Healthcare's MATERIAL WORLD

Providers who can successfully implement systems that integrate materials management with clinical and financial functions could realize big payoffs

BY SHARON WATSON

Hospital or warehouse? St. Francis Hospital in Tulsa, Okla., is a bit of both. ■ Three times a week, staffers take inventory on supply carts of bandages, gauze, ointments, tapes, syringes, surgical drapes and other raw materials necessary for daily work in the 900-bed hospital's patient care units. ■ These inventory staffers report to the hospital's materials management department — the behind-the-scenes materials and purchasing specialists who ensure that St. Francis' physicians, surgeons, nurses, lab technicians and even maintenance staffers and administrative workers receive supplies when and where they need them to create the hospital's product:

quality patient care.

The processes and systems that St. Francis uses to manage its materials are familiar to manufacturers and distributors far removed from healthcare. For instance, the inventory staffers key the item counts from supply carts into U.S. Data Corp.'s Current Inventory Management System with handheld devices. The system compares the numbers against the items' par values, then generates an electronic "pick list."

The list travels on a Novell, Inc. NetWare LAN to OrderMaster, a warehouse management system from Raymond Corp. that operates 50-ft-long automated supply carousels in St. Francis' warehouse. Lighted shelves in the carousel baskets tell workers which items to pick to restock patient supply carts.

OrderMaster also records transactions by order number and uploads that data through a homegrown interface to St. Francis' IBM 3090-based materials management system, IBM's COPICS, a building materials and inventory processing program the hospital modified for its needs. COPICS reduces the on-hand inventory balance, compares it with an item's reorder point and creates requisitions as necessary.

These are combined by vendor into purchase orders that COPICS loads into OnCall EDI, a PC-based electronic data interchange (EDI) system. OnCall EDI, from TSI International in Wilton, Conn., generates and transmits electronic purchase orders to St. Francis' EDI-ready vendors. For non-EDI vendors, the system automatically generates faxes. Staffers still place a few orders by phone, mainly to local vendors.

The system handles the basic materials management cycle but lacks robust integration and management reporting capabilities, said Joe Barnes, director of materials management at the hospital, which is searching for a new system to fill those gaps.

ONLY ONE OF MANY

St. Francis isn't alone in its search. Many healthcare providers are taking a new look at the impact of materials management on both financial and clinical operations. "In the past, providers installed systems very focused on purchasing and inventory to solve immediate business problems, but the systems don't necessarily communicate with accounting or clinicals," said Jennifer Langer, director of healthcare products strategy at PeopleSoft, Inc., an Atlanta-based materials management system vendor.

Such integration is critical for integrated delivery networks that want to mine all of their data to dig out their real costs and survive under managed care and capitated contracts.

"In a managed care environment, we in materials must have the systems to be able to look by doctor, by procedure, by covered life and see our costs for non-salaried expenses," Barnes said. In addition to this supply utilization data, he and other providers need to integrate materials data with clinical data to standardize materials orders by clinical procedures and pathways. They must also enforce those standards among ancillary care facilities, possibly with Internet-like solutions.

To fill these requirements, providers are implementing systems that integrate materials management staples — requisitions, inventory management, contract management — with financial functions such as accounts payable and activity-based accounting and clinical systems such as scheduling and care pathways. Such systems also incorporate workflow, EDI and Internet technology to streamline the procurement process.

The challenges in successfully exploiting the full capabilities of these integrated materials management systems are many. They're expensive, with an average price tag of about $300,000 to $400,000 for hardware and software. They cut across clinical and administrative boundaries, raising issues such as

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JIM PAILLOT

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ease of use for clinicians and control and audit trails for accounts payable. They require working with distributors and manufacturers to electronically connect to their systems to automate business transactions such as purchase orders, shipping documents and invoices.

Finally, a healthcare environment with its unexpected crises and complications doesn't always lend itself to the regimentation of a factory floor. "You'll always have situations in the O.R. that require flexibility," said Herb Sullivan, MIS director at Maimonides Medical Center in Brooklyn, N.Y. "You can't limit clinicians to two pads when a situation could come up where you need more."

But successful systems integration and streamlined materials management processes could pay off. An informal VHA, Inc. survey indicated that its 1,300 members alone, which represent about 21% of all U.S. hospitals, could save $50 million annually just by cleaning up errors in purchasing-related paperwork, said Paul Musgrave, senior director of program development at the Irving, Texas-based healthcare purchasing cooperative.

RE-ENGINEERING WORKFLOW

Like most healthcare providers, the first step toward these savings for Maimonides is streamlining its materials procurement process from patient units to a distributor's warehouse and back again.

The provider is replacing its 20-year-old Unisys Corp. mainframe and homegrown purchasing and accounting applications with an IBM RS/6000-based integrated materials management system from PeopleSoft, Sullivan said.

The hospital now creates a punch card for every supply order and line item so the mainframe can generate purchase orders. When shipments come in, receiving staffers pull the cards for a particular order, check them against shipping documents, handwrite any discrepancies on the cards, then send them to accounts payable for processing.

"It's a very inefficient, very labor-intensive process," Sullivan said. Under the first phase of implementing the PeopleSoft system, scheduled for year-end completion, Maimonides will eliminate the punch cards and automate receiving and warehousing functions. For example, the system will compare receiving documents against original purchase orders online.

Web Sites OF INTEREST

HEALTH INDUSTRY BUSINESS COMMUNICATIONS COUNCIL
www.hibcc.org
Information on Universal Product Numbers and the Health Industry Number system

NATIONAL ASSOCIATION OF PURCHASING MANAGEMENT
www.napm.org

VHA, INC.
www.vha.com
Large healthcare group purchasing cooperative

HEALTHCARE EDI COALITION
www.snider.net/hedic

WORKGROUP FOR ELECTRONIC DATA INTERCHANGE
www.wedi.org/wedi

Maimonides plans to add online user requisitioning by the end of 1997, routing those orders through approval levels via workflow scripts to the purchasing system. The center's expected savings from eliminating paper, errors and mainframe data center maintenance: about $1 million-plus per year.

THE EDI TRAIL

Providers are also saving money and increasing productivity by automating the business transactions that drive the materials management process. For example, Peninsula Regional Medical Center in Salisbury, Md., is implementing EDI with its key distributors and vendors, said Bill Hannemann, assistant director of materials management at the center.

To automate its most common business transactions with suppliers, Peninsula has implemented or is testing six of the American National Standards Institute's (ANSI) EDI transaction sets: the 810 invoice; the 812 credit/debit notice; the 820 corporate remittance advice; the 832 price/sales catalog; the 850 purchase order; and the 851 purchase order acknowledgment.

The EDI transaction sets are generated by materials management software from Minneapolis-based Lawson Software residing on a Digital Equipment Corp. Alpha 4100 server on an Ethernet TCP/IP network linking 50 Hewlett-Packard Co. PCs. The hospital is migrating to Microsoft Corp.'s Windows NT, said Raymond Shingler, Peninsula's chief information officer.

Of the electronic transactions, Hannemann said he is most excited about the ANSI 832. Peninsula receives an 832 pricing file from key vendors about every two weeks. Hannemann runs the new file against the old to check for pricing changes. Once the hospital approves these changes, they are loaded into the vendor contract, from which prices default to purchase orders as they're created. "Very seldom do you get a purchase order or invoice problem," he said.

That's quite a feat because with distributors and manufacturers offering thousands of products at various prices, depending on variables such as quantity ordered, it's virtually impossible for providers to keep up with price changes delivered on paper, tape or disk, said Stephen Rosen, director of marketing at TSI International. "All the benefits of EDI go away if there are errors in the electronic purchase order," he said. The 832 solves this issue.

The 832 and other EDI transactions also enable providers to use more cost-effective inventory strategies, such as just-in-time or stockless inventories, where a provider keeps only minimal stock on hand and delivers supplies just as they are needed.

Both Hannemann and Sullivan talked about the possibility of transmitting approved online requisitions directly from users to vendors without intervention from the purchasing area. "If we can create medical centerwide purchasing agreements and prenegotiated pricing with vendors, departments could become fully responsible for managing their own budgets and increase individual purchase

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Continued from page H10

orders to vendors via EDI," Sullivan said.

Hannemann is less optimistic about giving patient care units materials management control. He pointed out that each unit would need to verify materials received against purchase orders to guard against loss, a solution his accounting department has yet to agree to.

He's not alone. Accounting departments in general and their fondness for paper audit trails in particular are often obstacles to increasing EDI use, providers and materials management vendors say. For instance, many materials managers say they could eliminate invoices with key vendors and pay directly from the purchase order, a process called evaluated receipt settlement.

"We had talked about it, but I just don't see the financial people buying off on it," Hannemann said. "The accountants and auditors want to see someone's initials against a quantity received."

However, accountants and auditors may be pushed out of their reluctance to accept EDI as many of the industry's major distributors and manufacturers — Allegiance (formerly part of Baxter International), Abbott Laboratories, Owens & Minor — move to standardized EDI transaction sets. "With the exception of a few visionaries, EDI is always done to you," Rosen said. With hundreds of thousands of transactions a week, he said, big suppliers stand to gain significant cost savings by automating transactions. But healthcare providers, too, should benefit from increased efficiency, improved productivity and lower costs.

Vendors could also help speed EDI adoption by using uniform product codes and bar-coding supplies during production, VHA's Musgrave said. He added that he expects VHA and other group purchasing cooperatives to push vendors toward these tools by making their availability a contracting criterion.

Vendors are not the only parties being pushed to standardize. Providers are also creating standard materials requisitions based on procedures for which a patient is scheduled or a clinical pathway or treatment guideline associated with that procedure or diagnostic related group.

"The materials usage is a byproduct of the clinical pathways that say, 'Here's what you should use,' " said St. Francis' Barnes. With pathways in place, a provider could estimate materials quantities based on how often it performs a particular procedure under a specific managed care contract and use that data in contract negotiations.

Peninsula has begun developing both pathways and identifying supply utilization patterns. The hospital, in addition to its Lawson system for general medical supplies, uses Orsos from Atwork Corp. in Chapel Hill, N.C., for scheduling and materials control in its surgical and emergency departments and for tracking surgical supply utilization.

"With the Atwork and Lawson sys-

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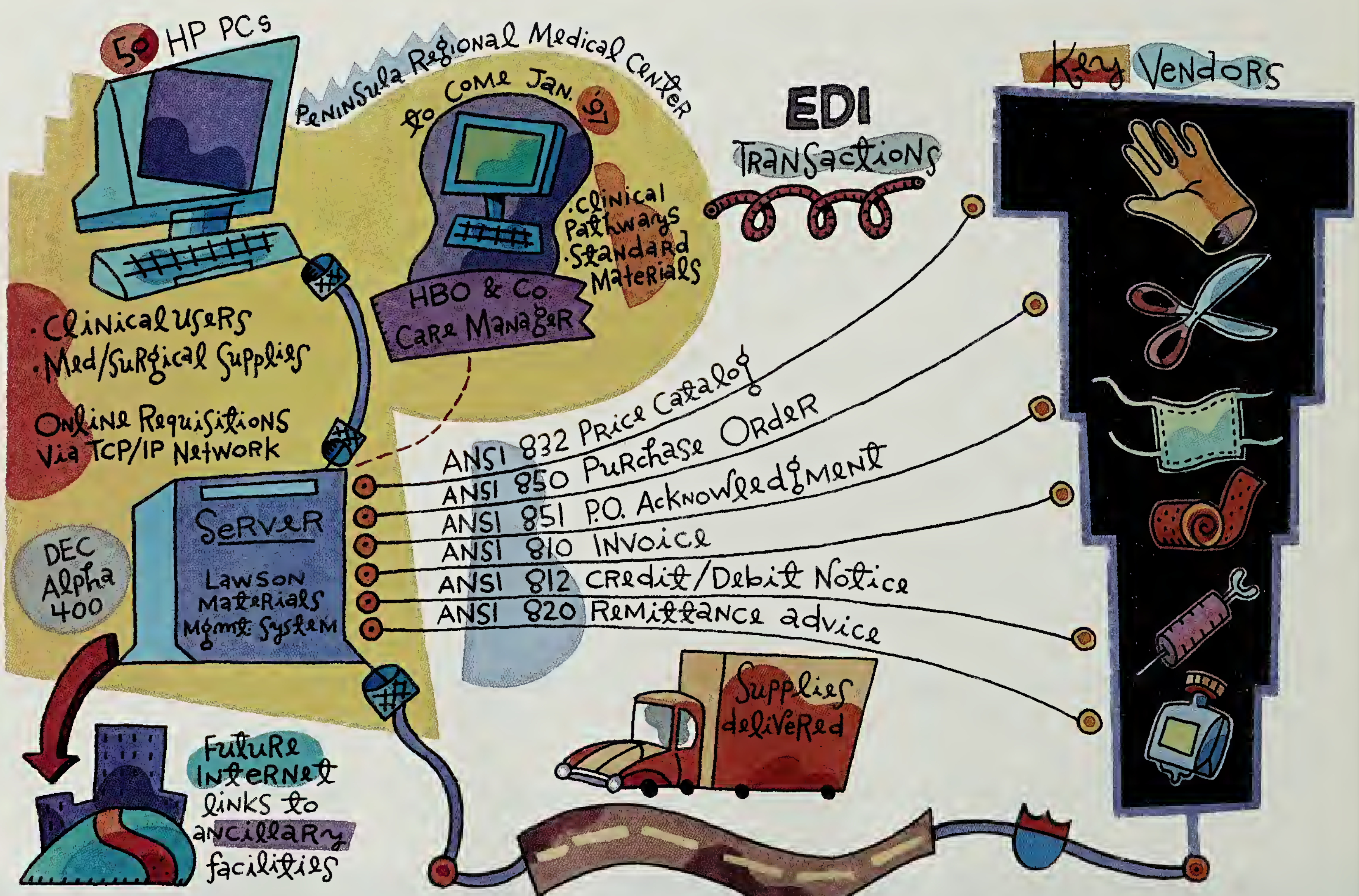
PENINSULA'S MATERIAL UNIVERSE

To automate its most common business transactions with suppliers, Peninsula is using/testing six ANSI EDI transaction sets



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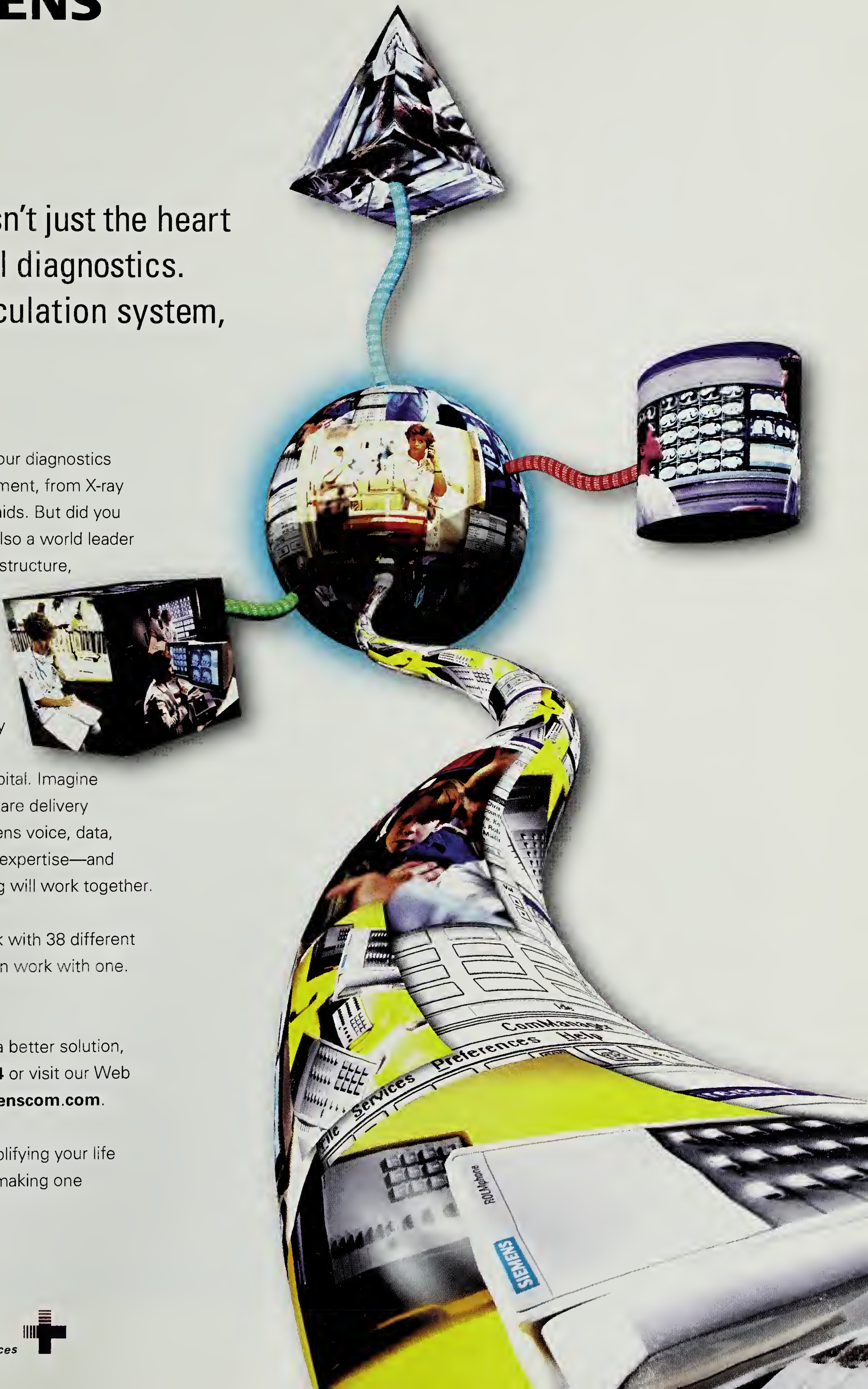

Continued from page H12

tems, we feel for the first time we'll be able to get to our unit costs," Shingler said. Both systems will also receive materials orders, based on clinical guidelines, from the hospital's HBO & Co. CareManager point-of-care system, being installed in January.

Yet while providers say a marriage of materials management and clinical pathways is inevitable, they aren't certain how standardized they can get, given that medicine is as much craft as science. "From where I'm sitting, the physician is still in control of treatment decisions, and those decisions generate the materials orders," Maimonides' Sullivan said.

'NET-BASED PURCHASING

Other groups that still largely control purchasing for themselves are the ancillary facilities that are becoming part of sprawling healthcare systems [HCJ, October 1996]. "With the rise of integrated delivery systems, materials management is being asked to centralize purchasing for multiple hospitals, clinics, skilled nursing facilities, home healthcare units — basically, the entire continuum of healthcare," said Tony Edwards, healthcare marketing manager at Lawson.

In the past, these ancillary care facilities have handled their own materials management, but that will change quickly as providers total up the costs of that autonomy, VHA's Musgrave said.

It's already changing at Peninsula, which has more than a dozen ancillary facilities in Delaware and Virginia as well as in its home state of Maryland. Its region encompasses metropolitan areas but also rural areas, such as the Eastern Shore, which just received its first Integrated Services Digital Network about six months ago, Shingler said.

To centralize ordering without incurring expensive dedicated line costs, Peninsula may put its materials management applications on an intranet. The fact that Lawson's materials management software has Hypertext Markup Language tools built in and the company is pursuing additional Internet connectivity was a major factor in the buying decision, Shingler said. He added that the hospital already has a firewall established for its Internet connections and would likely install another server inside the wall for the intranet.

Whether incorporating Internet-based ordering, EDI or clinical pathways, all agree that materials management has shifted from a focus on volume discounts and inventory management to a strategic function critical to controlling overall healthcare costs.

The industry is making this transition rapidly, with materials managers recognizing they'll be replaced if they can't adapt, said Dennis P. Orthman, a senior management consultant at Concepts In Healthcare, an Ashland, Mass.-based materials management consulting firm.

"They've seen they aren't well served by traditional purchasing and inventory systems when it comes to collecting supply utilization data, so they're moving to increasingly sophisticated systems," he said. "It's not necessarily a revolution, but it is a quick maturing of the industry." ■

WATSON IS A FREELANCE WRITER IN CHICAGO SPECIALIZING IN HEALTHCARE AND TECHNOLOGY.

Baptist Health Blesses SUPPLIES STANDARD

In many factories, each day the same parts go in the same place in the same order to make identical products. Such uniformity makes it easy to schedule production times, get volume discounts on parts, determine labor costs – and turn out a relatively inexpensive yet high-quality product.

Producing quality patient care will probably never be so regimented, given the variables of the human body. But wherever possible, many healthcare providers want to standardize care along clinical pathways that spell out processes as well as the products necessary to implement them.

"Some people are very leery of this because it sounds like assembly line medicine," said Frank Fernandez, corporate director of materials management at Baptist Health System of South Florida. "But it ensures that what needs to be done is actually done."

Baptist Hospital, the flagship of the four-hospital, Miami-based integrated delivery system, has been developing clinical pathways with standardized supplies since 1990. A committee of clinicians, administrators and materials management specialists looks at different case types and decides how to improve related quality measures such as length of stay, clinical outcomes and costs.

For big ticket pathway items, such as prostheses and surgical equipment, the group reviews inventory and cost data by surgeon and procedure, as well as clinical data and literature, then decides which materials to specify, said Denise H. Harris, R.N., director of care management at Baptist Hospital.

For example, the cardiac unit developed a protocol enabling the hospital to switch to an external blood gas measurement device during most open heart surgeries, thus eliminating the labor required to use an arterial blood gas measure that on paper wasn't much different in price than the external device.

Harris can't yet pinpoint which specific line item supply cost savings contributed to Baptist Hospital's $1.75 million pathway-induced cost savings in fiscal year 1995. She said she expects to know soon, in part by integrating TrendStar, a financial analysis tool from HBO & Co., with Baptist's materials management system, Nova, from Enterprise Systems, Inc. in Wheeling, Ill.

The three other members of the Baptist Health System will also use Nova and feed supply utilization data into a single Microsoft SQL database. Harris also plans to add HBO's Resource Utilization Analyst module to TrendStar, enabling her to track cost and charge data at line item levels. With these tools, Harris said she expects to see utilization rates and identify best practices across member hospitals.

"Quality is our No. 1 priority," she said. "With service and clinical excellence in place, what will follow is fiscal prudence and fiscal quality."

"Why

can't we determine which diagnostic procedure is most cost efficient?"

"Why

can't we improve our reimbursement cash flow?"

"Why

can't we reduce our inventory of supplies and drugs without causing chaos?"

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TRIALS *by*

RICHARD FERRIS SAYS CORNING BELIEVES ITS INTERNET/INTRANET ARCHITECTURE GIVES IT A POWERFUL STORY TO TELL CUSTOMERS ABOUT CUTTING TIME TO MARKET

JOHN RAE

INTERNET

PHARMACEUTICAL COMPANIES ARE EXPERIMENTING WITH TRANSMITTING CLINICAL TRIAL DATA OVER THE INTERNET/ INTRANETS TO CUT PAPER COSTS

By Linda Wilson

Imagine conducting a clinical trial for a promising new drug without generating any paper. Impossible, you say. Just think about the truckload of documentation typically necessary to satisfy Food and Drug Administration requirements, you add. Well, the truth is, an entire trial could be conducted electronically, thanks to the networking paradigm popularized by the Internet.

That's the thinking these days at Corning Pharmaceutical Services, Inc., a company that provides pharmaceutical companies with a variety of research-related services, including the management of clinical trials. Corning, based in Princeton, N.J., recently rolled out an intranet — an internal network modeled after the Internet — that some internal researchers use to access clinical trial data.

Corning is one of a number of companies in the pharmaceutical industry experimenting with internal intranets. But going to the next step — transmitting sensitive trial data among field researchers, clinical research organizations (CRO) and pharmaceutical companies over either the Internet or a private setup — is a tall order. "The pharmaceutical industry is very conservative," said Richard Ferris, manager of database integration at Corning. Executives worry about the security of patients' medical histories as well as data indicating how well a trial is going.

While the idea of paperless processes isn't new in the world of clinical trials, an intranet setup makes electronic processes a lot easier and less expensive to achieve. Intranet technology is tailor-made for the clinical trial process because a lot of remote researchers are connected to a central location, usually a CRO such as Corning. The centralized model dramatically cuts deployment, training and maintenance costs because it's not necessary to install lots of software on lots of computers.

"It is a lot easier to maintain a single application. It is a universal client," Ferris said. Another plus: "You don't have to worry about keeping two sets of data current [one at each remote site and one at Corning] because all of the data is centralized," he added.

TRIAL TERMINOLOGY

PHARMACEUTICAL COMPANY: Sponsors clinical trials to gather data

CLINICAL RESEARCH ORGANIZATION (CRO): Manages a clinical trial on behalf of the drug company

RESEARCHER: Typically a doctor associated with a university medical school

In addition to using an intranet infrastructure, using the Internet to transmit data among locations is quite inexpensive because Internet access providers charge a fixed amount per month, no matter how much data is shoved through the pipe. That's a potential boon for clinical trials, of course, which involve reams of data.

But whether the Internet or a private network is used to transmit information, the economic implications of following an Internet/intranet architecture strategy are enormous. In addition to cutting research costs directly via cheaper transmission rates and lower paper-related expenses, an all-electronic process would dramatically cut time to market for a new drug, allowing a pharmaceutical company more time to sell its product before the patent runs out.

While it's difficult to pinpoint, it's not unreasonable to think that three months or more could be chopped from the 15-year period most drugs spend in all phases of research and development, including clinical trials. There's a lot of money at stake, even during the course of a few months. For a coveted, blockbuster drug that represents a new type of treatment as opposed to a slightly better version of a drug already available, each day of exclusive sale represents about $3 million, said Dan Nutkis, director of emerging technologies in healthcare at Ernst & Young in Nashville, quoting a widely cited industry estimate.

Outside forces, particularly stock market investors, are fueling the urgency pharmaceutical executives feel to speed up the trial process. "Because drug prices are coming down as a result of managed care,

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there's a lot of pressure to get to market faster," said Marc Duey, president of ProMetrics Consulting, Inc. in Wayne, Pa., which specializes in pharmaeconomics and Internet/intranet technology.

It's difficult to know how many pharmaceutical companies, CROs or research centers are experimenting with Internet/intranet strategies. However, Duey said he believes some of the biggest players are at the very least thinking about the issue. No one, at least to Duey's knowledge, has rolled out a large-scale solution.

STILL FLYING LOW

Corning is among those in the pilot mode. The company believes the Internet/intranet architecture gives it a powerful story to tell customers interested in cutting time to market. "We have to prove to our clients that we are better than our competitors," Ferris said. However, Corning has not begun actively selling the program to customers yet. Ferris said he first must sell the program internally.

Corning launched its intranet pilot two months ago, following a development period that began in February. To begin with, 20 decision makers on research teams have been given access to data. The researchers are from Corning Besselaar, which manages the clinical trial research involving humans, and Corning SciCor, which provides laboratory services for clinical trials.

Using browser interfaces — either Navigator from Netscape Communications Corp. in Mountain View, Calif., or Explorer from Microsoft Corp. in Redmond, Wash. — researchers tap into a World Wide Web server, an Intel Corp. Pentium-based PC from Austin, Texas-based Dell Computer Corp. running Netscape Enterprise Server 2.0 on top of Microsoft's Windows NT 3.51. The Web server, in turn, connects to a database server, also a Pentium-based Dell PC, via a common gateway interface, a homegrown application written in Microsoft's Visual Basic. Data is stored in a Microsoft SQL Server 6.5 database and transmitted over a TCP/IP network running on both Token Ring and Ethernet LANs.

Researchers using the intranet are involved in one of two trials: one near the beginning of its life and one nearing completion. Those involved in the new trial can access data on patient enrollment figures and lab test results.

Already, the trial's database includes 57,000 records on lab test results. Ferris said he expects that count to climb into the millions. Researchers involved in the second, older trial are using the intranet to put together a New Drug Application, which Corning expects to submit electronically to the Food and Drug Administration by year's end.

Corning doesn't have a specific timetable for giving more in-house people access to the Web server. Instead, Ferris is demonstrating the setup to researchers on a team-by-team basis. "I am trying to develop a demand for it," he said. "I don't mandate to users what they should be doing." If and when an external customer agrees to pilot an Internet/intranet strategy, Ferris said he imagines the first step would be to link Corning and the pharmaceutical company researchers. Field researchers would be added as a second step.

IT COSTS WHAT?

Today, R&D for a typical new drug is time-consuming and expensive:

IT'S A PROCESS THAT spans 15 years, on average, compared with eight years in the 1960s

IT COSTS $500 MILLION, on average, compared with only $54 million in 1970

SOURCE: PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WASHINGTON

Corning hasn't decided whether data transmission should be handled through the Internet or a private network. While the Internet would undoubtedly be less expensive, it's also less secure and reliable than a private network. In addition, throughput varies widely.

"Mostly, we are talking about not going over the Internet," Ferris said, because the pharmaceutical companies he has talked to don't think the Internet is secure enough.

Other options include an 800 number that researchers would dial in to or some type of virtual network from a telecommunications vendor, Ferris said.

On the other hand, the Cleveland Clinic, a supersite that oversees a group of field research sites, isn't worried about Internet security. It has overseen the transmission of patient data from field sites to the clinic via the Internet since February 1994. The program began in pilot mode with five sites and expanded to all 15 involved in a multiyear study of dialysis patients in March 1995. However, the program hasn't expanded beyond the walls of the biostatistics department where it was created.

"That doesn't mean we don't worry about [security] and we don't think about it," said Martin Drabik, a systems analyst in charge of the Internet project for the Biostatistics Department at the Cleveland Clinic. "We just don't think many people would be interested in the data."

To send data to a file server, researchers enter a password. A second password is needed for them to view data stored on a clinic server. As a further privacy protection, patients are identified by number rather than by name.

Despite the pharmaceutical industry's overall concern about the security of electronic data transmission, cost pressures driven by the managed-care environment are likely to push more companies to explore Internet/intranet strategies.

Indeed, the scenario Corning envisions is just the beginning. In the future, patients are likely to be included in the electronic loop as well. The dual trends of providing medical care in the home and the increasing number of Internet-savvy patients argue for such an approach, ProMetrics Consulting's Duey said. Researchers "can post questions [to patients] and have them automatically sent out over E-mail." After all, why should patients travel to a clinic to provide data that could just as easily be provided from the comfort of home? This logical extension of electronic data delivery would benefit not only patients but also drug companies, which would reap the benefits of a corresponding decline in research expenditures. ■

WILSON IS A FREELANCE WRITER IN GLEN ELLYN, ILL.

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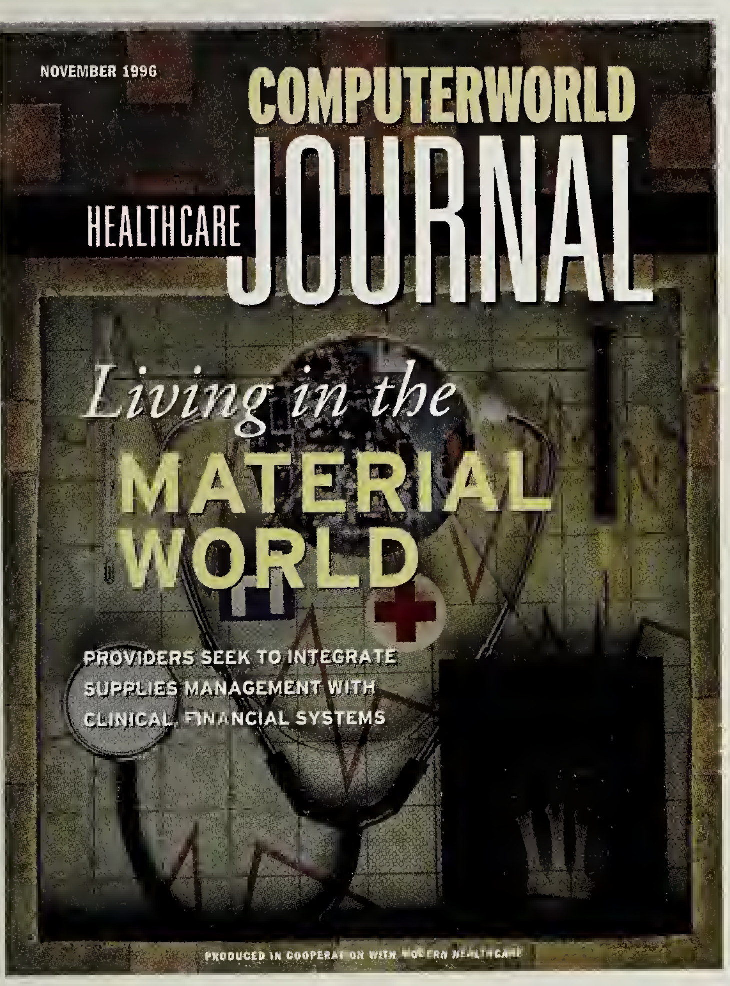

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